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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/562,191

10/26/2006

Vega Masignani

PP020667.0003

4113

27476

7590

03/29/2011

NOVARTIS VACCINES AND DIAGNOSTICS INC.

INTELLECTUAL PROPERTY- X100B

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Emeryville, CA 94662-8097

EXAMINER

FORD, VANESSA L

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

03/29/2011

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/562,191	<b>Applicant(s)</b> MASIGNANI ET AL.	
	<b>Examiner</b> VANESSA L. FORD	<b>Art Unit</b> 1645	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 January 2011.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6, 10, 13, 18, 19, 21, 22 and 24-32 is/are pending in the application.
- 4a) Of the above claim(s) 13, 21, 22 and 30-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 10, 18, 19, 26 and 29 is/are rejected.
- 7) ☒ Claim(s) 24, 25, 27 and 28 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 4/14/10 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **FINAL ACTION**

1. Applicant's amendment and response filed are acknowledged. Claims 1, 5 and 6 have been amended. Claims 7-9, 11-12, 14-17, 20 and 23 have been canceled. Claims 24-32 have been added.

Claims 21-22 and newly submitted claims 30-32 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on March 23, 2009.

Claims 1-6, 10, 18-19 and 24-29 are under examination.

### ***Rejections Maintained***

2. The rejection under 35 U.S.C. 102(a) is maintained for claims 1-6, 10 and 18-19 and newly submitted claims 26 and 29 for the reasons set forth on pages 3-4, paragraph 3 of the previous Office Action.

The following rejection is maintained and reiterated below:

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The claims are rejected under 35 U.S.C. 102(a) as anticipated Arico et al (*WO 03/010194 A2 published February 6, 2003*).

Independent claim 1 is drawn to a isolated immunogenic polypeptide comprising one or more of: (a) an amino acid sequence selected from the group consisting of SEQ ID Nos. 51, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18 and 54; (b) an amino acid sequence having at least 70% identity to a sequence as defined in (a);

Art Unit: 1645

and/or (c) an amino acid sequence comprising a fragment of at least 8 consecutive amino acids of a sequence as defined in (a).

Independent claim 5 is drawn to an isolated immunogenic polypeptide of the formula  $\text{NH}_2 \text{A-}\{-\text{X-L}\}_x\text{-B-COOH}$ .

Independent claim 6 is drawn to an isolated immunogenic polypeptide comprising the amino acid sequence  $\text{-A-W}_1\text{-W}_2\text{-W}_3\text{-W}_4\text{-B}$ .

Arico et al teach a polypeptide that comprising an amino acid sequence comprising a fragment of at least 8 consecutive amino acids of a sequence as defined in (a). (e.g. SEQ ID No:51). Arico et al teach NAdA adhesins A protein from *Neisseria meningitidis* (see the Abstract). Arico et al teaches immunogenic compositions that comprises the polypeptides of the invention (pages 15-18). See the sequence alignment below. The at least 8 consecutive amino acids of a sequence in SEQ ID NO.51 (elected sequence) are underlined below.

Query Match 33.0%; Score 422.5; DB 1; Length 355;

Best Local Similarity 38.7%;

Matches 103; Conservative 45; Mismatches 87; Indels 31; Gaps 7;

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Qy      18 TTVSNYALAAQAQAQVKKDELSELKKQVKEMDAAIDGI-----LDDNIAYEAE----- 66
      |  |           | : : : | : : | : : : |||:|           | :||  ||
Db      94 TKTVNENKQNVDAKVKAAESEIEKLTTKLADTDAALDATTNALNKLGENITTFAEETKTN
153

Qy      67 ---VDAKL-----DQHSAAALGRHTNRLNNLKTIAEKAKGDSSEALDKIEALEEQNDEF
116
      :| ||           |:|: |       : |: | | |:|       :||       | : : |
Db     154 IVKIDEKLEAVADTVDKHAEAFNDIADSLDETNTKADEAVKTANEAKQTAEETKQNVDD--
211

Qy     117 LADITALEEGVDGLDDDDITGIQDNISD----IEDDINQNSADIATNTAAIATHTQRLDNL
172
      | : | |       | : |       : :|       : :       ||||| | || : : |:|:|
Db     212 -AKVKAAETAA-GKAEAAAGTANTAADKAEAAKVTDIKADIATNKADIAKNSARIDSL
269

Qy     173 DNRVNNLNKDLKRGLAAQAALNGLFQPYNVGKLNLTAAVGGYKSQTAVAVGTGYRYNENI
232
      | | || | : : || |||:|||||||: |:|||||||:|:|:|:|:|:|:|
Db     270 DKNVANLRKETRQGLAEQAALSGLFQPYNVGRFNVTAAVGGYKSESAVAIGTGFRFTENF
329

Qy     233 AAKAGVAF--THGGSATYNVGVNFEW 256
      ||||| | : | || |:||||:|
Db     330 AAKAGVAVGTSAGSSAAYHVGNYEW 355

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Arico et al anticipate claimed invention.

Applicants Arguments:

Applicant urges that the Office asserts that Arico et al teach an amino acid sequence comprising a fragment of at least 8 consecutive amino acids of SEQ ID NO. 51. Applicant urges that they have amended claims to recite "at least 16 consecutive amino acids of SEQ ID NO. 51. Applicant urges that the presently amended claims are patentable over the prior art rejections.

Examiner's Response to Applicant's Arguments

Applicant's arguments filed October 6, 2010 have been fully considered but they are not persuasive.

Newly amended independent claim 1 is drawn to a isolated immunogenic polypeptide comprising one or more of: (a) an amino acid sequence selected from the group consisting of SEQ ID Nos. 51, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18 and 54; (b) an amino acid sequence having at least 70% identity to a sequence as defined in (a); and/or (c) an amino acid sequence comprising a fragment of at least 16 consecutive amino acids of a sequence as defined in (a).

The claims comprises fragments or sequences that are less than the full-length amino acid sequence as set forth in SEQ ID NO.51 (elected sequence). It should be noted that the Office views the recitation of "an amino acid sequence" as *less than* the full-length polypeptide or a fragment. Arico et al teach a polypeptide that comprising an amino acid sequence comprising a fragment of at least 8 consecutive amino acids of a sequence as defined in (a).(e.g. SEQ ID No:51) and these fragments (see underlined

fragments in sequence alignment above) are also amino acid sequences that are "an amino acid sequence having at least 70% identity to a sequence as defined in (a)" because these fragments are 100% identical to SEQ ID NO.51. Thus, Arico et al anticipate the amended claims.

In view of all of the above, this rejection is maintained.

3. The rejection under 35 U.S.C. 102(b) is maintained for claims 1-6, 10 and 18-19 and newly submitted claims 26 and 29 for the reasons set forth on pages 5-6, paragraph 4 of the previous Office Action.

The following rejection is maintained and reiterated below:

The claims are rejected under 35 U.S.C. 102(b) as anticipated Fraser et al (*WO 99/57280 A2 published November 11, 1999*).

Independent claim 1 is drawn to a isolated immunogenic polypeptide comprising one or more of: (a) an amino acid sequence selected from the group consisting of SEQ ID Nos. 51, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18 and 54; (b) an amino acid sequence having at least 70% identity to a sequence as defined in (a); and/or (c) an amino acid sequence comprising a fragment of at least 16 consecutive amino acids of a sequence as defined in (a).

Independent claim 5 is drawn to an isolated immunogenic polypeptide of the formula  $\text{NH}_2 \text{ A-}\{-\text{X-L}\}_x\text{-B-COOH}$ .

Independent claim 6 is drawn to an isolated immunogenic polypeptide comprising the amino acid sequence -A-W<sub>1</sub>-W<sub>2</sub>-W<sub>3</sub>-W<sub>4</sub>-B. Fraser et al teach polypeptides comprising Neisserial polypeptides (see the Abstract). Fraser et al teaches immunogenic compositions that comprises the polypeptides of the invention (pages 33-36). See the sequence alignment below. The at least 8 consecutive amino acids of a sequence in SEQ ID NO.51 (elected sequence) are underlined below.

Art Unit: 1645

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Query Match          32.5%;   Score 416;   DB 1;   Length 364;
Best Local Similarity 38.1%;
Matches 104;   Conservative 45;   Mismatches 86;   Indels 38;   Gaps
8;

Qy      18  TTVSNYALAAQAQAQAQVKKDELSELKKQVKEMDAAI---DGILD-----DNIAYE 64
      |  |           | : : : | : : | : : : ||| :   |  ||           : ||
Db      96  TKTVNENKQNVDAKVKAAESEIEKLT'TKLADTDAALADTDAALDETTNALNKLGENITTF
155

Qy      65  AE-----VDAKL-----DQHSAAALGRHTNRLNNLKTIAEKAKGDSSEALDKIEAL
109
      ||           : ||           | : : |           : | :   | | : : |   : ||   |
Db     156  AEETKTNIVKIDEKLEAVADTVDKHAEAFNDIADSLDETNTKADEAVKTANEAKQTAEET
215

Qy     110  EEQNDEFLADITALEEGVDGLDDDDITGIQDNISD---IEDDINQNSADIATNTAAIATH
165
      : :   |   | : | |   |   :   |   :   : |   :   :   ||||| | || :
Db     216  KQNV D---AKV KAAETAA-GKAEAAAGTANTAADKAEAVAAKVTDIKADIATNKADIKN
271

Qy     166  TQRLDNLDNRVNNLNKDLKRGLAAQAALNGLFQPYNVGKLNLTAAVGGYKSQTAVAVGTG
225
      : | : : ||   | || | : : : || | ||| : || || || || : | : || || || : || |
Db     272  SARIDSLDKNVANLRKETRQGLAEQAALS GLFQPYNVGRFNV TAAVGGYKSESAVAIGTG
331

Qy     226  YRYNENIAAKAGVAF--THGGSATYNVGVNFEW 256
      : :   || || || || ||   : | || | : || || : ||
Db     332  FRFTENFAAKAGVAVGTSSGSSAAYHVGVNVEW 364

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Applicants Arguments:

Applicant urges that the Office assets that Fraser et al teach an amino acid sequence comprising a fragment of at least 8 consecutive amino acids of SEQ ID NO. 51. Applicant urges that they have amended claims to recite “at least 16 consecutive amino acids of SEQ ID NO. 51. Applicant urges that the presently amended claims are patentable over the prior art rejections.

Examiner's Response to Applicant's Arguments

Applicant's arguments filed October 6, 2010 have been fully considered but they are not persuasive.

Newly amended independent claim 1 is drawn to a isolated immunogenic polypeptide comprising one or more of: (a) an amino acid sequence selected from the group consisting of SEQ ID Nos. 51, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18 and 54; (b) an amino acid sequence having at least 70% identity to a sequence as defined in (a); and/or (c) an amino acid sequence comprising a fragment of at least 16 consecutive amino acids of a sequence as defined in (a).

The claims comprises fragments or sequences that are less than the full-length amino acid sequence as set forth in SEQ ID NO.51 (elected sequence). It should be noted that the Office views the recitation of "an amino acid sequence" as *less than* the full-length polypeptide or a fragment. Fraser et al teach a polypeptide that comprising an amino acid sequence comprising a fragment of at least 8 consecutive amino acids of a sequence as defined in (a).(e.g. SEQ ID No:51) and these fragments (see underlined fragments in sequence alignment above) are also amino acid sequences that are "an amino acid sequence having at least 70% identity to a sequence as defined in (a)" because these fragments are 100% identical to SEQ ID NO.51. Thus, Fraser et al anticipate the amended claims.

In view of all of the above, this rejection is maintained.



***Status of Claims***

4. No claims allowed. Claims 24-25 and 27-28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Conclusion***

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to VANESSA L. FORD whose telephone number is (571)272-0857. The examiner can normally be reached on 9 am- 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571.272.0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Vanessa L. Ford/  
Primary Examiner, Art Unit 1645  
March 23, 2011

Application/Control Number: 10/562,191  
Art Unit: 1645

Page 10